RES. INST. USA use by user-facilities, and manufacturers for DATORY reporti reporting

· Pp	,
RIUSA1999006580	
//Dist report #	·

of <u>4</u>				FBA Um Only
C. Suspect medication)B(S)			
1. Name (give labeled streng #1 TYLOX (capsu	th & mfr/labeler, il		ETAMINOPHI	EN)
*2 TYLENOL W/CO			INE)	
2. Dose, (requency & route us		3. Therapy dates	(if unknown, give	duration)
" oral		#1 ??/???		
*2 oral		#2 ??/???	/??	
4. Diagnosis for use (indicate #1 UNKNOWN	ion)		5. Event abated a stopped or des	e reduced
12 UNKNOWN			#1 yes n	apply
6. Lot# (if known) #1	7. Exp. de	ete (if known)	8. Event reappear	no docsn't apply red after
#2	#2		reintroduction	—
9. NDC#- for product proble	ms only (if known))	#1 Uyes Un	o Todoesn'i
		-	#2 ∐yes ∏n	o doesn't apply
10. Concomitant medical produ No Concomitan		apy dates (elictive i	remain of event)	
		NOV 2	L 1999	
	مين دون ميد ۾ آمون	ISSE EVENT REI	OMNO SYSTEM	
G. All manufacturers		161	CHIMANA	
l. Contact office - name/address	(& mfring	rite for devices)	2. Phone m	mber
R.W. JOHNSON USA DIV. OF ORTHO CORP. 920 U.S. Route P.O. Box 300 Raritan NJ 088 USA (Informing Un	PHARMAC e 202 869		3. Report st (check all force study	ource I that apply) ign y ature
Date received by manufactures	5 (A)NDA	• 88-790		essional
11/11/99	IND		l 🗀 user	[acitity
. If IND, protocol #	PLA		— Li come	eschiative
	ļ		_ distri	butor
. Type of report	pre-1	938 ye	other	. !
(check all that apply)	OTC produ	act 🗌 ye	٠	
- - -	1	erse event term(s)		
10-day periodic		DULT RESI TRESS SYI		j
Initial Collow-up#	_1_ 2) F		RY DEPRESS	SION
. Mfr. report number		NCREASED	PT () N	1
RIUSA1999006580	1 - 1	ONFUSION		
F. Initial reporter			(Cont)
Name, address & phose # Dr. Toby Litov National Capit Georgetown Uni 3800 Reservoir Washington, DC USA	al Poiso versity Road NW	Hospital		199.)
Health professional? 3.	Occupation	4.	Initial reporter als sent report to FDA	•
🛣 yes 🗌 no	Physicia	n ,		∑ unk

				50
attent infor	mation			•11
rationt identifier	2. Age at time		3. Sex	4. Weight
	of event: 4	8 yr	[female	UNK_Ibs
?-?	or			or
in confidence	Date of birth:	??/???/??	T male	UNK kgs
B. Adverse even				
	and/or	Product problem	(e.g., defects/m	(firmations)
1. Adverse event		Froduct problem	(e.g., onecigring	enuncuous)
Outcomes attributed: (check all that apply)	lo adverse event	disability		
	222/22	congenital :	anomaly	
=	(markbaylyr)	. =	ervention to prevent	ı
life-threatening		permanent	impairment/damage	
tospitalization -	initial or prolonged	other:		
		- 14		
3. Date of event ??/?	??/??	4. Date of this report	11/15/	99
(meldeyfyr)		(ma/day/yr)		
5. Describe event or prol	blem			
Report pub	lished in	1993 Annua	l Report	of
the Americ	an Associ	ation of Po.	ison Cont	rol
		ta Collecti		ι
unspecifie	. n 40-ye d) died f	ear-old pations in	restion o	f
acetaminop	hen with	oxycodone, a	and	-
acetaminop	hen with	codeine. In	tent of	
was acute/	is unknow chronic	m. Exposure	to meal	ation
was acate,	CIII OIII C			
Additional	Informat	ion received	1 11-Nov-	99: A
48 year old	d white π	ale was four	nd in his	home
with a dec	reased le by ambula	vel of consonce nce to the e	ciousness Pmerdency	. не
		was lavaged		
ivated o	charcoal.	Pills found	in his	home
		phen with ox		
		codeine #3, ocarbamol ar		ne
secobarbit	al sodium	. Due to the	history	of
repeated a	cetaminop	hen ingestic	on.	i
(Acetamino	phen 4 mc	g/mL), he wa	s starte	d on
following	an initia	mg/kg every 1 loading do	se of 14	urs 0
mar/kar. By t	the follo	wing dav art	erial blo	ood
gases were	pH, 7.4	5; pCO2, 38 tion, 91%. H	mmHg; pO	2, 57
mmHg; and ()2 satura	tion, 91%. H	l e was (Con	- \
6. Relevant tests/inborate	ry data, includ	ing dates		
Chest x-ray	v was con	sistent with	ARDS	į
(Lab data			·	j
j	•			
				ĺ
				}
				· ·
			•	
			(Con	-,
7. Other relevant history,		-	(c.g., allergies	
pregnancy, smoking and	alcohol use, hepatic	renal dysfunction, etc.)		
unknown				
				į
		•		İ
i				1
	Subr	nission of a report does not	constitute an	

admission that medical personnel, user facility,

distributor, manufacturer or product caused or

contributed to the event.



fe report # PRIUSA1999006580	
F/Dist report 9	-
	- 1

MEDICAL	PRODUCTS REF	UA1180 /RU	u Arm m	Page	2_ of 4_				FDA Une C
	2. Age at time of event:	-11	3. Sex	4. Weight	C. Suspect of Name (give)	abeled strength &	mfr/labeler, if i	mown) (DROCHLOF	
	Date		male	or	M SECONA				(TDE)
In confidence B. Adag 1 Sections	of birth; or product prob	lem		kgs	2. Dose, frequenc				C.C
I. Adverse event	and/or	Product problem	(e.g., defects/m	alfunctions)	*3 oral		1	frum/to (or best catio	
Outcomes attributed to (check all that apply)	adverse event	disability			4 oral			13 ??/??? 14 ??/???	
death	(mortic y/y r)	Congenital a	•		4. Diagnosis for as	se (indication)		1.17.11.1	5. Event abated after per
if ife-threatening		permanent is	ervention to prevent mpairment/damage		44 UNKNOWI				stopped or dose reduced #3yesnodoesn
<u> </u>	nitial or prolonged	other:			1		The state of the s		# C C C
3. Date of avent (mother):		4. Date of this report			6. Lot# (if known #3)	7. Exp. date	(il known)	8. Event reappeared after
5. Describe event or probl	em	(makin yéye)			£4	· 	14		reintroduction
					9. NDC# - for pro	oduct problems o	nly (if known)		#3 yes no deem
					10.0		· · · · · · · · · · · · · · · · · · ·	$ \mathbb{I}$	no doesn't
					10. Concomitant m	edical products	and therap	y dates (exclude tre	
								NOV 2	2 1 1999
							•	POSE EVENE	OFFICE
								- TOT EVENI	perching system
					1. Contact office - na		10 -6:		
					Comment only a	ne/sectres	(& miring site	for devices)	2. Phone number
, <i>y</i>									3. Report source
									(check all that apply)
									study
					-				literature
									consumer health
					4. Date received by ma	nufacturer	5. (A)NDA#		professional
6. Relevant tests/laboratory	data, including dates						IND#		user facility
				1	6. If IND, pretocol#		PLA#		company representative
					7. Type of report	-	pre-1938	yes	distributor
					(check all that apply)		OTC	yes	U other:
					5-day 15-0		8. Adverse	event term(s)	
					∐ 10-day ∐ peni				
7. Other relevant history, inc	Indine precipine medica	d conditions	(2.2.28			ow-up #]		
pregnancy, smoking and alc	ohol use, hepstic/renal dysf	function, etc.)	(e.g., allergies, r	ace.	9. Mfr. report number				1
					F. Initial reporte 1. Name, address & pho		•		
					1. I value, audiress or prio	ne #			
				. []				1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
1								NIC.	IV 1 9 1990
	C. S. J. J.				Market and a	Т.		NU.	1
erane f	admission that	a report does not con medical personnel, u	ser facility,		. Health professional?	3. Oceu	petion	4. In	nt reporter also
3500A Facsamile	distributer, ma contributed to	nufacturer or produ the event.	ct caused or	L	yes no				yes o o unk



TOUDISCON PHARM, RES. INST. USA or use by user-facilities, ors and manufacturers for

NDATORY reporting

Page 3 of 4

RIUSA1999006580	
F/Dist report #	
	FDA Line Only

A RESICAL	PROBUCTS REPOR			, -				
aftent infor			3. Sex	4. Weight	C. Suspect medicatio 1. Name (give labeled strength	h & mfr/labeler, if	known)	
. Patient identifier	2. Age at time of event:		J. Sex	1	* ROBAXIN (METH	OCARBAM	OL)	
	or ————			or lbs				1
	Date		male	kgs	#6			
In confidence	of birth: For product proble	11			2. Dose, frequency & route use	:d	3. Therapy date: treats (or best ex	
Adverse event		oduct problem	(e.g., defects/m	alfunctions)	*5 oral		#5 ??/???	
2. Outcomes attributed					**		#6	
(check all that apply)	to Buverse event	disability			4. Diagnosis for use (indicati	ion)		5. Event abated after use
death	(maldaylyr)	congenital a	nomaly ervention to prever	nt	#5 UNKNOWN			stopped or dose reduced
life-threatening			mpairment/damage		76			#5 yes no doesn't
hospitalization	- initial or prolonged	other:						#6 yes no doesn't
3. Date of		4. Date of			6. Lot & (iCknown) #5	7. Exp. d	late (if known)	8. Event reappeared after
event	1	this report				_		reintroduction
5. Describe event or pro	hlen	1 (#6	#6		#5 yes no doesn't
2. Describe event or bro					9. NDC # - for product problet	ms only (if knows	1)	#6 yes no docsn't
								ar 1) to 1 to 1
					10. Concomitant medical produ	ucts and the	crapy dates (exclude	treatment of event)
							• •	
					(in All) and and the Company			
	•				G. All manufacturers 1. Contact office - name/address		gille by devices)	2. Phone number
			,			5	A Name of Street	
						NOV 9 1	1000	3. Report source
and the same						NOV 2 1	1333	(check all that apply)
								Corcign
					ADVER	SE EVENT REI	POITING SYSTE	study
					-			literature
								consumer
		•				16		health professional
					4. Date received by manufactur (mattaytyr)	er S. (A)NI	DA#	user facility
	story data. including date					IN	D#	company representative
6. Relevant tests/labora	story data, including date	•			6. If IND, protocol #	PL	A#	representative
							>1938	distributor distributor
i					7. Type of report	1	_	other:
					(check all that apply)	pri	oduct	yes
					5-day 15-day	8. A	dverse event term(s)
					10-day periodic			
					Initiat I follow-up #			
				·				
7. Other relevant histo	ry, including preexisting med and alcohol use, hepatic/renal d	ical conditions lysfunction, etc.)	(e.g., aller	gies, race,	9. Mfr. report number			•
pregnaticy, shoung	and account that, acquires the	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				Ì		,
1					F. Initial reporter			
					1. Name, address & phone #		711/15	O Part to Line
				•			· I	100 t 9 1990
								-
I							· ~,,	
					7 Month and and and	3. Occupation		4. Initial reporter also
		e of a report does r that medical perso			2. Health professional?	J. Occupation		4. Initial reporter also sent report to FDA
·		nat medical person, manufacturer or			yes bo			yes no unk
1500A Facsimile	contribute	d to the event.						



ation Sheet for FDA-3500A Form

Page 4___ of <u>4</u>___

Mfr. report #: PRIUSA1999006580

Date of this report: 11/15/99

B. Adverse event or product problem

B.5 Describe event or problem (Cont...)

confused and hallucinating. His liver function studies included: ammonia, 90 mcg/dL; LDH, 1580 lU/L; ALT, 1305 lU/L; and AST, 2290 lU/L. He was started on lactulose. His respiratory status declined and he was intubated and placed on a ventilator. By the third day of hospitalization, his ammonia had dropped to 55 mcg/dL from a peak of 117 mcg/dL and clinically he was improving. He extubated himself but his respiratory status declined off the ventilator and he was resintubated. He completed the 18 dose course of N-acetylcysteine. His ammonia began to increase (90 mcg/dL) and his respiratory status further declined. Chest x-ray was consistent with Adult Respiratory Distress Syndrome. He expired on the seventh day of hospitalization. of hospitalization.

B.6 Relevant tests/laboratory data, including dates (Cont...)

Lab Result:

2.13

Test date Test name Test result Normal value ??/??/93 ALANINE AMINOTRANSPERASE 1305 IU/L (international unit/liter) 90 mcg/dL **AMMONT A** (microgram/deciliter) AMMONIA 55 mcg/dL (microgram/decili-(third day of hospitalization) AMMONIA 117 mcg/dL (microgram/deciliter) 2290 IU/L ASPARTATE AMINOTRANSFERASE (international
unit/liter) BLOOD GAS 38 mmHg (millimeter mercury) PCO2 BLOOD GAS 57 mmHg (millimeter mercury) PO2 BLOOD GAS 91 % (percent) 02 SATURATION ALTERS EVENT TIPE SEED. LACTIC DEHYDROGENASE 1580 IU/L (international unit/liter) PH 7.45

C. Suspect medication (Cont...)

Seq No. C.1 Suspect medication Approval information ANDA#

: 2

: TYLENO! W/CODEINE NO. 3 (tablet) (ACETAMINOPHEN/CODEINE)

: 85-055

G. All manufacturers

8. Adverse event term(s)

6) STUPOR

Source of report (Literature):

Seq No. Author Journal title

Toby Litovitz

1993 Annual Report of the American Association of Poison Control Centers National Data Collection

System 94

:

12(5)

NOV 2 9 1999

ımber title

From 546 To 515 American Journal of Emergency Medicine